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10/566,829	01/31/2006	Chikara Jin	TOYA145.001APC	7514

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
4161	

NOTIFICATION DATE	DELIVERY MODE
06/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/566,829	JIN ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08). Paper No(s)/Mail Date *3/09/2006 and 1/31/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-8 are currently pending and the subject of this Office Action. This is the first Office Action on the merits of the claims.

Information Disclosure Statement

2. All references have been considered.

Priority

3. The earliest effective filing date afforded the instantly claimed invention has been determined to be 07/12/2005 as to claims 1-8. Acknowledgment is made of Applicant's claim for foreign priority pursuant to 35 U.S.C. 119(a) and 365(b) based on a prior application filed in Japan on 7/12/2004. The certified copy has been filed in parent Application No. PCT/JP05/12835, filed on 07/12/2005.

Election/Restrictions

4. Applicant's election with traverse of granisetron, carrageenan, combination of kappa and iota carrageenan, and locust bean gum in the reply filed on 5/01/2008 is acknowledged. Applicant does not provide any grounds upon which the traversal is based and thus is not found persuasive. The requirement is still deemed proper and is therefore made FINAL.

5. The elected species read upon claims 1-8. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/07/2008.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1, 3-4 and 8 rejected under 35 U.S.C. 102(b) as being anticipated by *Johnson et al* (US 6,316,027).**

8. Instant claims 1-3 are drawn to a jellied composition for oral administration comprising a 5-HT_3 receptor antagonist (specifically granisetron), a gelatinizing agent, and water, wherein the composition has a pH of 7 or less, and a light blocking container. *Johnson et al* teach a pharmaceutical composition for oral administration comprising a 5-HT_3 receptor antagonist (specifically granisetron), a gelatinizing agent (specifically gelatin), and water (Example 15, Columns 16-17), having a pH of 3.0 (Column 10, Lines 21-23, which is part of Example 1; Col. 13, lines 65-68 indicates that the formulations of the remaining examples, which includes Example 15, was prepared using the process described in Example 1). Additionally, *Johnson et al* teach the composition "dosed into each one of a series of pre-formed blister pockets having a pocket diameter of 16 mm... [and] sealed with lidding foil consisting of a paper/foil laminate (20 gm aluminum)" (Column 10, Lines 27-39) and "a pack containing the portions... a blister pack" (Column 12, Lines 15-17) which encompasses a light blocking container. Accordingly, *Johnson et al* anticipate each of the elements of instant claims 1, 3 and 8.

9. In addition to gelatin as a gelatinizing agent, *Johnson et al* additionally teach "carrageenans" (Column 6, Lines 15-18). As recognized by *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), claims to a species are anticipated where the prior art teaches a genus embracing a limited number of members closely related to each other in structure and the properties possessed by the genus of the prior art is that disclosed for the claimed species. In the instant case, *Johnson et al* teach a limited number of closely related gelatinizing agents which includes the instantly claimed species carrageenan. In view of the limited number of gelatinizing agents useful in the composition taught by *Johnson et al*, a person of ordinary skill in the art would immediately envisage using as a gelatinizing agent carrageenans. Accordingly, *Johnson et al* anticipate instant claim 4.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claims 1-5 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over *Johnson et al* (US 6,316,027) in view of *Hai* (US 6,767,558) and *Fukuchi et al* (Pub No US2005/0175628).**

13. The limitations of claims 1, 3-4, and 8 are taught by Johnson et al., as discussed above. However, the composition of *Johnson et al* does not teach the inclusion of a reductant (i.e., an antioxidant) as recited by instant claim 2. As taught by *Hai* (US 6,767,558) "The desirability of providing pharmaceutical formulations in which an oxidation-susceptible active drug ingredient or ingredients are protected against oxidative degradation inherent to prolonged storage is a concept well known to, and appreciated by, one of ordinary skill in the art. Anti-oxidants commonly employed in various pharmaceutical formulations may include, inter alia, vitamin E, ascorbic acid, BHT (butylated hydroxytoluene), BHA (butylated hydroxyanisole), and the like." Since developing pharmaceutical compositions capable of prolonged storage is desirable, it would have been obvious to a person of ordinary skill in the art to combine a reductant, as taught by *Hai*, with the composition taught by *Johnson et al*. Accordingly, claim 2 is obvious.

14. As discussed above *Johnson et al* specifically disclose a composition which includes carrageenan. However, *Johnson et al* are silent as to the type of carrageenan whereas instant claim 5 recites the gelatinizing agent is kappa- and iota-carrageenan (claim 5). *Fukuchi et al* teach a jellied pharmaceutical composition which includes carrageenan "wherein the carrageenan is iota-carrageenan, or a combination of iota-

carrageenan with kappa-carrageenan" (claim 2). In view of the fact that *Johnson et al* disclose carrageenan, and in view of *Fukuchi et al* which teaches the use of a combination of iota-carrageenan with kappa-carrageenan, a person of ordinary skill in the art would immediately envisage using as a gelatinizing agent a mixture of κ- and ι-carrageenan (as recited by instant claim 5) in the teaching of *Johnson et al*.

15. **Claim 6 rejected under 35 U.S.C. 103(a) as being unpatentable over *Johnson et al* (US 6,316,027), in further view of *Ninomiya et al* (US 5,932,235).** *Johnson et al* teach a composition for oral administration as discussed above. However, they don't specifically teach locust been gum as a thickener as recited by instant claim 6. *Ninomiya et al* teach "a jellied medical composition for oral administration" (Column 1, Lines 6-7) comprising a gelatinizing agent (specifically carrageenan), water, and a thickener (specifically locust bean gum) (Examples 1-7, Columns 10-12). In the instant case, both *Johnson et al* and *Ninomiya et al* teach jellied compositions for oral administration containing thickeners which are functional equivalents of each other. Thus, it would have been obvious to a person of ordinary skill in the art to use locust bean gum, as taught by *Ninomiya et al*, and which is a functional equivalent of gelatin, as a thickener in the invention of *Johnson et al*. Accordingly, claim 6 is obvious.

16. **Claim 7 rejected under 35 U.S.C. 103(a) as being unpatentable over *Johnson et al* (US 6,316,027), in further view *Zabik and Aldrich* (J Food Science, 30(5):795-800, 1965).**

17. *Johnson et al* teach a composition for oral administration as discussed above. However, they don't teach the inclusion of a water-soluble salt of potassium or calcium as recited by instant claim 7. However, *Johnson et al* do teach as matrix forming agents, inorganic salts such as sodium phosphate and sodium chloride (Column 6, Lines 21-23). Moreover, *Zabik and Aldrich* teach that "increasing the concentrations of each potassium salt, used in combination with kappa-carrageenan, produced gels which have significantly higher breaking-force and total energy values and lower deformation readings" (abstract). Thus, one of ordinary skill in the art would not feel limited to sodium phosphate and sodium chloride as inorganic salts as taught by *Johnson et al* and would have found it obvious at the time the invention was made to use salts of potassium or calcium as matrix forming agents. Accordingly, claim 7 is obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. **Claims 1-8 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 and 7 of U.S. Patent No. 5,932,235 in view of *Johnson et al* (US 6,316,027), *Fleming et al* (Am J Health-Syst Pharm 52(5):514-516, 1995), *Quercia et al* (provided in Applicant's IDS filed 1/31/2006), *Hai* (US 6,767,558), *Zabik and Aldrich* (J Food Science, 30(5):795-800, 1965), and FDA *Guidance for Industry on Container Closure Systems for Packaging Human Drugs and Biologics* (May, 1999).**

19. Instant claims 1-8 are drawn to a jellied composition for oral administration comprising a 5-HT_3 receptor antagonist (specifically granisetron), a gelatinizing agent (specifically carrageenan, more specifically a mix of kappa- and iota-carrageenan),

water, a reductant, a thickener (specifically locust bean gum), and a water soluble salt of potassium or calcium, wherein the composition has a pH of 7 or less, and a light blocking container. Claims 1 and 7 of the '235 patent recite a jellied medical composition for oral administration comprising carrageenan and locust bean gum, and a container. However, claims 1 and 7 of the '235 patent do not recite the inclusion of a 5-HT_3 receptor antagonist (such as granisetron), carrageenan wherein the carrageenan is specifically a mix of kappa- and iota-carrageenan, a reductant, and water, wherein the composition has a pH of 7 or less, as recited by the instant application. Additionally, the '235 patent does not recite that the container is light blocking.

20. Although the '235 patent (*Ninomiya et al*) does not teach the inclusion of a 5-HT_3 antagonist, as taught by *Johnson et al*, there are numerous advantages to an anti-emetic, specifically a 5-HT_3 antagonist and more specifically granisetron, formulated in "fast-dispersing dosage forms" which anticipate a jellied composition. Specifically, *Johnson et al* teach that "such a fast-dispersing dosage form of the anti-emetic would have many of the advantages associated with such formulations, such as increased bioavailability, dose reduction, ease of administration, etc" (Column 7, Lines 50-56). Considering that *Ninomiya et al* teach a composition "which is easily taken by patients of advanced age or patients with dysphagia" (Column 1, Lines 7-10), it would have been obvious to a person of ordinary skill in the art to include in the composition as a medically effective component an anti-emetic, specifically a 5-HT_3 antagonist and more specifically granisetron, as taught by *Johnson et al* for the reasons taught by *Johnson et al*, to achieve the desired results as stated by *Ninomiya et al*.

21. Additionally, it would have been obvious to a person of ordinary skill in the art to include water in the invention recited by claim 1 of the '235 patent. As disclosed by *Fukuchi et al*, and also disclosed in the '235 patent, a "medical composition in the form of a jelly... includes a liquid which is usually used as a dispersion medium of a jelly composition, for example water" (Paragraph 0026).

22. Although *Ninomiya et al* do not teach a composition wherein the pH is 7 or less, it is well known in the art that the pH of a pharmaceutical composition can influence drug stability, storage and preservation. Moreover, *Fleming et al* specifically teach that pH influences the stability of the 5-HT_3 receptor antagonist ondansetron, which has a similar mechanism of action as granisetron. Specifically, *Fleming et al* teach that "the stability of ondansetron is pH dependent, with precipitation of ondansetron occurring in solutions with a pH of 5.7 or more" (Page 515, Column 2, Paragraph 2). Additionally, *Quercia et al* teach that the 5-HT_3 receptor antagonist granisetron in oral liquid formulation is stable in the pH range from 2.7 to 2.8. Thus it would have been obvious to a person of ordinary skill in the art to formulate the composition taught by *Johnson et al* having a pH of 7 or less.

23. Additionally, the composition of *Ninomiya et al* does not teach the inclusion of a reductant as recited by instant claim 2. As discussed above, *Hai* (US 6,767,558) teach "The desirability of providing pharmaceutical formulations in which an oxidation-susceptible active drug ingredient or ingredients are protected against oxidative degradation inherent to prolonged storage is a concept well known to, and appreciated by, one of ordinary skill in the art. Anti-oxidants commonly employed in various

pharmaceutical formulations may include, inter alia, vitamin E, ascorbic acid, BHT (butylated hydroxytoluene), BHA (butylated hydroxyanisole), and the like." Since developing pharmaceutical compositions capable of prolonged storage is desirable, it would have been obvious to a person of ordinary skill in the art to combine a reductant, as taught by *Hai*, with the composition taught by *Ninomiya et al*.

24. As discussed above, *Ninomiya et al* teach "a jellied medical composition for oral administration" (Column 1, Lines 6-7) which includes a gelatinizing agent (specifically carrageenan) and a thickener (specifically locust bean gum) (Examples 1-7, Columns 10-12) as recited by instant claims 4 and 6. More specifically, *Ninomiya et al* teach "it is preferrable to use a base containing carrageenan and locust bean gum" and that "carrageenan includes κ, ι, and λ type" (Column 4, Lines 13-20). Although *Ninomiya et al* teach that the κ type is preferred, they specifically teach that "any of these types of carrageenan can be used in the jellied medical composition for oral administration of the present invention" (Column 4, Lines 18-20). Moreover, *Fukuchi et al* teach a jellied pharmaceutical composition which includes carrageenan "wherein the carrageenan is iota-carrageenan, or a combination of iota-carrageenan with kappa-carrageenan" (claim 2). In view of the limited number of possibilities of carrageenan disclosed by *Ninomiya et al*, and especially in view of *Fukuchi et al* which teaches the use of a combination of iota-carrageenan with kappa-carrageenan,a person of ordinary skill in the art would immediately envisage using as a gelatinizing agent a mixture of κ- and ι-carrageenan (as recited by instant claim 5) in the teaching of *Ninomiya et al*.

25. *Ninomiya et al* also do not recite the inclusion of a water soluble salt of potassium or calcium as recited by instant claim 7. However, *Johnson et al* teach as matrix forming agents, inorganic salts such as sodium phosphate and sodium chloride (Column 6, Lines 21-23). Thus it would be obvious to a person of ordinary skill in the art to use inorganic salts in the invention of *Ninomiya et al*. Furthermore, one of ordinary skill in the art would not feel limited to sodium phosphate and sodium chloride as inorganic salts as discussed above in view of *Zabik and Aldrich*, and would find it obvious to also include salts containing potassium or calcium.

26. *Ninomiya et al* teach a container (Column 7, Lines 3-4). However, *Ninomiya et al* are silent as to the light blocking ability of the container. As taught by FDA *Guidance for Industry on Container Closure Systems for Packaging Human Drugs and Biologics*, "A container closure system should provide the dosage form with adequate protection from factors (eg, temperature, light)..." (Page 7). Accordingly, it would have been obvious to a person of ordinary skill in the art to make the container taught by *Ninomiya et al* light blocking.

27. For the reasons discussed above it would have been obvious to a person of ordinary skill in the art to include in the composition recited by claim 1 of the '235 patent a 5-HT_3 receptor antagonist such as granisetron, carrageenan wherein the carrageenan is specifically a mix of kappa- and iota-carrageenan, water and a reductant. Also, it would have been obvious to a person of ordinary skill in the art to formulate the composition recited by claim 1 of the '235 patent wherein the composition has a pH of 7 or less for the reasons discussed above. Finally, it would have been obvious to make

the container recited by claim 7 of the '235 patent a light blocking container for the reasons discussed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571)270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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